

AMENDED CLAIMS

[received by the International Bureau on 20 October 1998 (20.10.98);
original claims 1,2,4,10,11 and 13 amended; remaining claims unchanged
(2 pages)]

1. A pharmaceutical excipient useful in the formulation of
dry powder inhaler compositions, characterized in that it comprises a
particulate roller-dried anhydrous ~~X~~-lactose.

5 2. An excipient according to claim 1, characterized in that
the roller-dried ^{anhydrous}~~X~~-lactose particles have a size between 50 and 250
micrometers.

3. An excipient according to claim 2, characterized in that
said particles have a size comprised between 100 and 160 micrometers.

10 4. An excipient according to any of claims 1 to 3,
characterized in that said particulate roller-dried anhydrous ~~X~~-lactose
has a rugosity comprised between 1.9 and 2.4.

5. A dry powder inhaler pharmaceutical composition,
characterized in that it comprises a mixture of an active ingredient and
15 an excipient as claimed in any one of claims 1 to 4.

6. A composition according to claim 5, characterized in that
the active ingredient is a particulate solid with a particle diameter
comprised between 0.5 and 6 micrometers.

20 7. A composition according to either of claims 5 and 6,
characterized in that the weight ratio of the active ingredient in relation to
the excipient is of from 0.1/100 to 50/100.

8. A composition according to any of claims 5 to 7,
characterized in that the active ingredient is selected from the group
comprising mucolytics, steroids, sympathomimetics, proteins, peptides
25 and inhibitors of mediator's release.

9. A composition according to claim 8, characterized in that
the active ingredient is a mucolytic agent such as L-lysine N-
acetylcysteinate.

30 10. A composition according to claim 9, characterized in
that it comprises a mixture of particulate L-lysine N-acetylcysteinate and

roller-dried anhydrous ~~γ~~-lactose constituted by particles of 100 to 160 micrometers in size and of 1.9 to 2.4 in rugosity, the weight ratio of L-lysine N-acetylcysteinate in relation to the roller-dried anhydrous ~~γ~~-lactose being of from 1/2 to 1/6.

5 11. A composition according to claim 9, characterized in that the weight ratio of L-lysine N-acéthylcysteinate in relation to the roller-dried anhydrous ~~γ~~-lactose is comprised between 1/2 and 1/4.

12. A composition according to claim 11, characterized in that said weight ratio is of the order of 1/4.

10 13. A process for the preparation of an excipient as claimed in any one of claims 1 to 4, characterized in that anhydrous ~~γ~~-lactose in a powder form is dissolved in demineralised water, fed between two counterrotating drums, which are steam heated and then screeped from the surface of the drums.

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